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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/319,736 | 08/02/1999 | ELISABETH WOLPERT | 000500-182 | 3510 |

21839 7590 06/02/2004

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| EXAMINER |
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LACOURCIERE, KAREN A

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| ART UNIT | PAPER NUMBER |
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1635

26

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/319,736

Applicant(s)

WOLPERT ET AL.

Examiner

Karen A. Lacourciere

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 143-162 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 143-162 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 143-145, drawn to a method of impairing cellular peptide processing by administering a substance that inhibits the function of TAP, classified in class 514, subclass 2.
- II. Claims 143-145, drawn to a method of impairing cellular peptide processing by administering a substance that inhibits the expression of TAP, classified in class 536, subclass 24.5.
- III. Claims 143, 146 and 147, drawn to a method of impairing cellular peptide processing by administering a substance that inhibits the function of the proteasome, classified in class 514, subclass 2.
- IV. Claims 143, 146 and 147, drawn to a method of impairing cellular peptide processing by administering a substance that inhibits the expression of the proteasome, classified in class 536, subclass 24.5.
- V. Claims 148-150, 153 and 154, drawn to a method of identifying cells that activate CD8+ T lymphocytes by administering a substance that inhibits the activity of TAP, classified in class 514, subclass 2.
- VI. Claims 148-150, 153 and 154, drawn to a method of identifying cells that activate CD8+ T lymphocytes by administering a

Art Unit: 1635

substance that inhibits the expression of TAP, classified in class 514, subclass 44.

- VII. Claims 148, 151-154, drawn to a method of identifying cells that activate CD8+ T lymphocytes by administering a substance that inhibits the activity of the proteasome, classified in class 514, subclass 2.
- VIII. Claims 148, 151-154, drawn to a method of identifying cells that activate CD8+ T lymphocytes by administering a substance that inhibits the expression of the proteasome, classified in class 514, subclass 44.
- IX. Claims 155, 156 and 158, drawn to a process of stimulating immunological effector cells using cells with impaired cellular peptide processing, classified in class 435, subclass 6.
- X. Claims 157, 160 and 161, drawn to cells impaired in cellular peptide processing, classified in class 435, subclass 325.
- XI. Claims 159 and 162, drawn to a substance that impairs cellular peptide processing, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to

Art Unit: 1635

materially different methods with different modes of operation. For example, the methods of Group I operate by inhibiting the function of TAP and are practiced by administering different compounds than the methods of Group II, which operate by inhibiting the expression of TAP.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different modes of operation. For example, the methods of Group I operate by inhibiting the function of TAP and are practiced by administering different compounds than the methods of Group III, which operate by inhibiting the function of the proteasome.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different modes of operation. For example, the methods of Group I operate by inhibiting the function of TAP and are practiced by administering different compounds than the methods of Group IV, which operate by inhibiting the expression of the proteasome.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

Art Unit: 1635

806.04, MPEP § 808.01). In the instant case the different invention are drawn to methods with different effects. For example, the methods of Group I have the effect of impairing cellular peptide processing, whereas the methods of Group V, which have the effect of identifying cells which activate CD8+ T lymphocytes.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group I operate by inhibiting the function of TAP and have the effect of impairing cellular peptide processing are practiced by administering different compounds than the methods of Group VI, which operate by inhibiting the expression of TAP and have the effect of identifying cells which activate CD8+ T lymphocytes.

Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group I operate by inhibiting the function of TAP and have the effect of impairing cellular peptide processing are practiced by administering different compounds than the methods of Group VII, which operate

Art Unit: 1635

by inhibiting the function of the proteasome and have the effect of identifying cells which activate CD8+ T lymphocytes.

Inventions I and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group I operate by inhibiting the function of TAP and have the effect of impairing cellular peptide processing are practiced by administering different compounds than the methods of Group VIII, which operate by inhibiting the expression of the proteasome and have the effect of identifying cells which activate CD8+ T lymphocytes.

Inventions I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group I have the effect of impairing cellular peptide processing, whereas the methods of Group IX have the effect of identifying immunological effector cells.

Inventions I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in

Art Unit: 1635

a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells of Group X can be used in a materially different method than that of the methods of Group I. For example, the cells of Group X can be used in a method of purification to isolate epitopes involved with cellular peptide processing.

Inventions I and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group XI can be used in a materially different method, for example, the substances which are antibodies can be used in affinity purification, the antisense substances can be used as primers.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group II operate by inhibiting the expression of TAP and are practiced by administering different compounds than the methods of Group III, which operate by inhibiting the function of the proteasome.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

Art Unit: 1635

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different modes of operation. For example, the methods of Group II operate by inhibiting the expression of TAP and are practiced by administering different compounds than the methods of Group IV, which operate by inhibiting the expression of the proteasome.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to methods with different effects and different modes of operation. For example, the methods of Group II have the effect of impairing cellular peptide processing and operate by inhibiting the expression of TAP, whereas the methods of Group V, which have the effect of identifying cells which activate CD8+ T lymphocytes and operate by inhibiting the function of TAP.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to methods with different effects. For example, the methods of Group II operate have the effect of impairing cellular peptide processing which is different than the methods of Group VI, which have the effect of identifying cells which activate CD8+ T lymphocytes.

Art Unit: 1635

Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group II operate by inhibiting the expression of TAP and have the effect of impairing cellular peptide processing are practiced by administering different compounds than the methods of Group VII, which operate by inhibiting the function of the proteasome and have the effect of identifying cells which activate CD8+ T lymphocytes.

Inventions II and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group II operate by inhibiting the expression of TAP and have the effect of impairing cellular peptide processing are practiced by administering different compounds than the methods of Group VIII, which operate by inhibiting the expression of the proteasome and have the effect of identifying cells which activate CD8+ T lymphocytes.

Inventions II and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

Art Unit: 1635

806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group II have the effect of impairing cellular peptide processing, whereas the methods of Group IX have the effect of identifying immunological effector cells.

Inventions II and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells of Group X can be used in a materially different method than that of the methods of Group II. For example, the cells of Group X can be used in a method of purification to isolate epitopes involved with cellular peptide processing.

Inventions II and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group XI can be used in a materially different method, for example, the substances which are antibodies can be used in affinity purification, the antisense substances can be used as primers.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

Art Unit: 1635

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different modes of operation. For example, the methods of Group III operate by inhibiting the activity of the proteasome and are practiced by administering different compounds than the methods of Group IV, which operate by inhibiting the expression of the proteasome.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to methods with different effects and different modes of operation. For example, the methods of Group III have the effect of impairing cellular peptide processing and operate by inhibiting the function of the protease, whereas the methods of Group V, which have the effect of identifying cells which activate CD8+ T lymphocytes and operate by inhibiting the function of TAP.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to methods with different effects. For example, the methods of Group III operate have the effect of impairing cellular peptide processing which is different than the methods of Group VI, which have the effect of identifying cells which activate CD8+ T lymphocytes.

Art Unit: 1635

Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different effects. For example, the methods of Group III operate have the effect of impairing cellular peptide processing whereas the methods of Group VII have the effect of identifying cells which activate CD8+ T lymphocytes.

Inventions III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different modes of operation and different effects. For example, the methods of Group III operate by inhibiting the function of the protease and have the effect of impairing cellular peptide processing and are practiced by administering different compounds than the methods of Group VIII, which operate by inhibiting the expression of the proteasome and have the effect of identifying cells which activate CD8+ T lymphocytes.

Inventions III and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group III have the

Art Unit: 1635

effect of impairing cellular peptide processing, whereas the methods of Group IX have the effect of identifying immunological effector cells.

Inventions III and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells of Group X can be used in a materially different method than that of the methods of Group III. For example, the cells of Group X can be used in a method of purification to isolate epitopes involved with cellular peptide processing.

Inventions III and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group XI can be used in a materially different method, for example, the substances which are antibodies can be used in affinity purification, the antisense substances can be used as primers.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to

Art Unit: 1635

methods with different effects and different modes of operation. For example, the methods of Group IV have the effect of impairing cellular peptide processing and operate by inhibiting the expression of the protease, whereas the methods of Group V, which have the effect of identifying cells which activate CD8+ T lymphocytes and operate by inhibiting the function of TAP.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to methods with different effects. For example, the methods of Group IV have the effect of impairing cellular peptide processing which is different than the methods of Group VI, which have the effect of identifying cells which activate CD8+ T lymphocytes.

Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different effects. For example, the methods of Group IV have the effect of impairing cellular peptide processing whereas the methods of Group VII have the effect of identifying cells which activate CD8+ T lymphocytes.

Inventions IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

Art Unit: 1635

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different effects. For example, the methods of Group IV have the effect of impairing cellular peptide processing whereas the methods of Group VIII have the effect of identifying cells which activate CD8+ T lymphocytes.

Inventions IV and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group IV have the effect of impairing cellular peptide processing, whereas the methods of Group IX have the effect of identifying immunological effector cells.

Inventions IV and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells of Group X can be used in a materially different method than that of the methods of Group IV. For example, the cells of Group X can be used in a method of purification to isolate epitopes involved with cellular peptide processing.

Art Unit: 1635

Inventions IV and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group XI can be used in a materially different method, for example, the substances which are antibodies can be used in affinity purification, the antisense substances can be used as primers.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to methods with different modes of operation. For example, the methods of Group V have the effect of identifying cells which activate CD8+ T lymphocytes and operate by inhibiting the function of TAP which is different than the methods of Group VI, which operate by inhibiting the expression of TAP.

Inventions V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group V operate by inhibiting the function of TAP whereas the methods of Group VII operate by inhibiting the function of the protease.

Inventions V and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different modes of operation. For example, the methods of Group V operate by inhibiting the function of TAP and are practiced by administering different compounds than the methods of Group VIII, which operate by inhibiting the expression of the proteasome.

Inventions V and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group V have the effect of whereas the methods of Group IX have the effect of identifying immunological effector cells.

Inventions V and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells of Group X can be used in a materially different method than that of the methods of Group V. For example, the cells of Group X can used

Art Unit: 1635

in a method of purification to isolate epitopes involved with cellular peptide processing.

Inventions V and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group XI can be used in a materially different method, for example, the substances which are antibodies can be used in affinity purification, the antisense substances can be used as primers.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different modes of operation. For example, the methods of Group VI operate by inhibiting the expression of TAP whereas the methods of Group VII operate by inhibiting the function of the protease.

Inventions VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different modes of operation. For example, the methods of Group VI operate by inhibiting the expression of TAP and are

Art Unit: 1635

practiced by administering different compounds than the methods of Group VIII, which operate by inhibiting the expression of the proteasome.

Inventions VI and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group VI have the effect of identifying cells which activate CD8+ lymphocytes, whereas the methods of Group IX have the effect of identifying immunological effector cells.

Inventions VI and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells of Group X can be used in a materially different method than that of the methods of Group VI. For example, the cells of Group X can be used in a method of purification to isolate epitopes involved with cellular peptide processing.

Inventions VI and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

Art Unit: 1635

instant case the product of Group XI can be used in a materially different method, for example, the substances which are antibodies can be used in affinity purification, the antisense substances can be used as primers.

Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention are drawn to materially different methods with different modes of operation. For example, the methods of Group VII operate by inhibiting the function of the proteasome and are practiced by administering different compounds than the methods of Group VIII, which operate by inhibiting the expression of the proteasome.

Inventions VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group VII have the effect of identifying cells which activate CD8+ T lymphocytes whereas the methods of Group IX have the effect of identifying immunological effector cells.

Inventions VII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

Art Unit: 1635

instant case the cells of Group X can be used in a materially different method than that of the methods of Group VII. For example, the cells of Group X can be used in a method of purification to isolate epitopes involved with cellular peptide processing.

Inventions VII and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group XI can be used in a materially different method, for example, the substances which are antibodies can be used in affinity purification, the antisense substances can be used as primers.

Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects. For example, the methods of Group V have the effect of whereas the methods of Group IX. Inventions VIII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells of Group X can be

Art Unit: 1635

used in a materially different method than that of the methods of Group VIII. For example, the cells of Group X can be used in a method of purification to isolate epitopes involved with cellular peptide processing.

Inventions VIII and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group XI can be used in a materially different method, for example, the substances which are antibodies can be used in affinity purification, the antisense substances can be used as primers.

Inventions IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells of Group X can be used in a materially different method than that of the methods of Group IX. For example, the cells of Group X can be used in a method of purification to isolate epitopes involved with cellular peptide processing.

Inventions IX and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

Art Unit: 1635

another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group XI can be used in a materially different method, for example, the substances which are antibodies can be used in affinity purification, the antisense substances can be used as primers.

Inventions X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells of Group X can be used in a materially different method than that of the methods of Group XI. For example, the cells of Group X can be used in a method of purification to isolate epitopes involved with cellular peptide processing.

Claim 143 link(s) inventions I and II and III and IV. Claims 144 and 145 are generic to Group I and II and claims 146 and 147 are generic to Group III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 143. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are

Art Unit: 1635

presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 148 link(s) inventions V and VI and VII and VIII. Claims 149, 150, 153 and 154 are generic to Groups V and VI and claims 151-154 are generic to Groups VII and VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 148. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Art Unit: 1635

This application contains claims directed to the following patentably distinct species of the claimed invention: For Group I, Group II, Group V and Group VI, the following distinct species are disclosed : ICP47 of HSV type 1, IE12 of HSV type 2, a gene encoding a TAP inhibitor, a nucleotide sequence that is complementary to mRNA or DNA sequences encoding TAP, antisense oligonucleotides and RNA destroying ribozyme. For Group III and Group IV and Group VII and Group VIII, the following species are disclosed: peptide aldehyde Z-Leu-Leu-H, Lactacystin, DNA encoding a proteasome inhibitor, a nucleotide sequence that is complementary at least in part to the mRNA or DNA sequences encoding proteasome, antisense oligonucleotides and RNA destroying ribozyme.

If Applicant should elect any of Groups I-VIII, Applicant must further elect one species as discussed above, wherein the species corresponds to the elected Group.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form

Art Unit: 1635

or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1635

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (571) 272-0759. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Lacourciere
June 1, 2004



KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER